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09/866,892	05/29/2001	Stephen Christopher Porter	8600-0015	5581

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EXAMINER	
IZAGUIRRE, ISMAEL	
ART UNIT	**PAPER NUMBER**
3765	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/866,892	PORTER, STEPHEN CHRISTOPHER
	Examiner	Art Unit
	Ismael Izaguirre	3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on 2/3/02 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims

Summary

Claims 1 and 27 are the independent claims under consideration in this Office Action.

Claims 2-26 and 28-49 are the dependent claims under consideration in this Office Action.

Concerning the amendment to the language of claim 27, the following is submitted for applicant's consideration:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27-49 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In claim 27, the claim positively recites deploying the three-dimensional device into a body cavity. Claiming the body cavity in combination with the insertion therein of the device is not considered patentable subject matter under 35 USC 101 since the grant of a limited exclusive property right in a human being is prohibited by the constitution. Replacing "and is deployed" by "is adapted to be deployed" is suggested.

Concerning the language of the claims, the amendments made to the claims are appreciated and the following is submitted for applicant's consideration:

Claim Rejections - 35 U.S.C. § 112

Claims 13 and 39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to the claims, line 1, there is no proper antecedent basis for the words "the liking elements".

Concerning the Patentability of the claims, the following newly found prior art and art of record is applicable as follows:

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7,11,13,14,16,24,26-33,37,39,40,42,45,47 and 48 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ritchart et al. (4,994,069).

Ritchart et al. teach a vaso-occlusive device and method for forming the device (re claims 1,26,27 and 48). Ritchart et al. teach an occlusive element 48 (figure 6, for example) comprising an injection-molded material formed into a three-dimensional configuration. Ritchart et al. teach the device comprising a wire 46 being formed from a flexible, preshaped polymer tube (see column 6, lines 16-30). The singly molded tube (re claims 11 and 37) is taught as including an inside or an outside coating of collagen (column 5, last line) for coacting with the aneurysm structure (re claims 2,3,28,29 and

47). Ritchart et al. teach that the occluding device includes a coil structure where, for example, when viewed along the longitudinal axis would include channels between the coils in the orthogonal direction to the longitudinal coil axis 23 (figure 2b) and where it can further include squeezed coils (linking elements- re claims 13 and 39) at points 32 which provide the structure with a plurality of shaped structures (straight sections) linked in series by the squeezed sections (re claims 4-7 and 30-33).

The coil is taught as being movable through a catheter 12 where its end is mechanically engaged by a pusher (figure 7) and it is provided with a severable joint, at 62, which is mechanically detachable (re claims 14,16,40 and 42). The occluding element is further provided with a radio-opaque material for making it visible fluoroscopically (column 1, lines 47-48) where it can include an appropriate radio-opaque resin material (re claims 24 and 45).

Claims 1,4-7,9,12-17,22-27,30-33,35,38-43,45,46 and 48 are rejected under 35 U.S.C. § 102(b) as being anticipated by Palermo et al. (5,925,059).

Palermo et al. teach a vaso-occlusive embolic coil device and method for forming the device (re claims 1,26,27 and 48). Palermo et al. teach an occlusive element 102 (figure 1A, for example) comprising an injection-molded material formed into a three-dimensional configuration. Palermo et al. teach that the occluding device includes a first structure (the coil 102) and spherically shaped ends (306 and 308) (re claims 9,12,22,35 and 38). The ends 306 and 308 include means (such as 310 and 318) for linking a plurality of coils to each other in an "end-to-end train" configuration for filling the aneurysm (from column 7, line 8) (re claims 9 and 33). Each coil includes a coil

structure where, for example, when viewed along the longitudinal axis would include channels between the coils in the orthogonal direction to the longitudinal coil axis (figure 1A) and where it can further include wire connecting such ends (figures 16-18) which provide the structure with a plurality of shaped structures linked in series (re claims 4-7 and 30-33).

The coil is taught as being movable through a catheter 120 (figure 7A) where the ends of the coils are connected mechanically to the pusher and this is provided with a severable joint, at 107 (re claims 14,16,40 and 42). Further, Palermo et al. teach connections and means for disconnecting the coils as including the use of a current and heat (column 2, lines 23 and 56) (re claims 15,17,41 and 43). The occluding element is further provided with a radio opaque material for making it visible fluoroscopically (column 1, lines 47-48) where it can include platinum or gold, for example (column 7, lines 28-30) (re claims 24,45 and 46). As noted before each coil is connected to another coil in and end-to-end fashion and Palermo et al. further teach that the connection point includes a wire therein (figure 17) and/or including soldering (from column 5, line 1) (re claims 13,23,25 and 39).

Claims 27,28,30-32,40,41 and 45-47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Berenstein et al. (5,690,666).

Berenstein et al. teach a vaso-occlusive embolic coil device and method for forming the device (re claim 27). Berenstein et al. teach an occlusive element 100 and 202 (figure s 1 and 2, for example) comprising a biocompatible polymer formed into a three-dimensional configuration. Berenstein et al. teach that the occluding device

includes a first structure (the coil 100) and spherically shaped ends (208) and a braided overlying structure 202 where the wire comprises an absorbable, bioactive component of Dacron for promoting thrombosis (re claims 28 and 47). The coil includes a coil structure where, for example, when viewed along the longitudinal axis would include channels between the coils in the orthogonal direction to the longitudinal coil axis (figure 1, for example.

Berenstein et al. teach that a coil is movable through a catheter (column 2, lines 37-54) where the end of the coil is mechanically connected to a pusher and this is provided with a severable joint (re claim 40). Further, Berenstein et al. teach the use of a current for disconnecting the bond (re claim 41). The occluding element is further provided with a radio opaque material for making it visible fluoroscopically (column 4, lines 23-28) where it can include platinum or gold, for example (re claims 45 and 46).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6,9,14-17,19-21,24-32,40-43,45 and 47-49 are rejected under 35 U.S.C. § 102(e) as being anticipated by Porter et al. (6,547,804).

Porter et al. teach a vaso-occlusive balloon device and method for forming the device (re claims 1,26,27 and 48). Porter et al. teach an occlusive element 10 (figure 1A, for example) comprising an injection-molded material (from column 3, lines 32-35) formed into a three-dimensional configuration. Porter et al. teach that the occluding device includes a biodegradable hydrogel component (from column 1, line 63-65) (re claims 2,3,28,29 and 47) with the device having, when viewed along the longitudinal axis, orthogonal channels micro machined by using a laser into the balloon structure (from column 3, lines 8-14) (re claims 4-6,19,21,30-32 and 49) and where those channels may be formed by etching the material (column 3, line 311) (re claim 20),

The balloon element is taught as being movable through a catheter and is connected to the pusher 14 and this is provided with a severable joint (re claims 14 and 40). Further, Porter et al. teach means for disconnecting the balloon as including the use of mechanical, thermal, chemical and electrolytic means (column 5, lines 19-30) (re claims 14-17, and 40-43). The occluding element is further provided with a radio opaque material for making it visible fluoroscopically (column 3, lines 36-40 (re claims 24 and 45). Porter et al. teach that the balloon has a wire within the molded structure (figure 1A, for example) (re claim 25).

Claims 27,30-34,38,45,46 and 49 are rejected under 35 U.S.C. § 102(e) as being anticipated by Mitelberg et al. (6,613,074).

Mitelberg et al. teach a vaso-occlusive device and method for forming the device (re claim 27). Mitelberg et al. teach an occlusive element 30 (figure 6, for example) comprising a micro machined (laser cut) material (from column 4, line 34) formed into a three-dimensional configuration (re claim 49). Mitelberg et al. teach the element having, when viewed along the longitudinal axis, orthogonal channels micro machined by using a laser into the structure for forming liked elements in the shape of ovoids and pyramids (figure 5 and 5A, for example) (re claims 30-34,36). The occluding device is formed of at least two major components comprising a stent-like portion (with the micro-machined sections) and an occluding film 38 (re claim 38) and includes a radio-opaque material, such as gold (from column 5, lines 1-7) (re claims 45 and 46).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8,10,11,14,15,19,21,22,24,26-34,36,37,40,41, and 45-49 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Marotta et al. (6,261,305) in view of Igaki (6,200,335).

Marotta et al. disclose the invention substantially as claimed. Marotta et al. teach a vaso-occlusive prosthesis and method for forming the device (re claims 1,26 and 27).

Marotta et al. teach an occlusive element 105 (figure 6, for example) comprising a three-dimensional configuration. Marotta et al. teach the device comprising a material including a tube 5 or wire structure (figure 16) being formed from a flexible, preshaped polymer tube micro-cut by a laser (see column 7, lines 63-66) (re claims 19,21 and 49). The singly formed tube (figure 6) is taught as one embodiment and is taught formed of a plurality of shaped structures attached in series (figure 11 or 16, for example) (re claims 7,11,33 and 37). Marotta et al. teach the occluder as including the use of biodegradable materials (from column 7, line 56-58) and is bioactive (from column 8, lines 34-40) for coacting with the aneurysm structure (re claims 2,28 and 47).

Marotta et al. teach that the occluding device includes a tubular structure where, for example, when viewed along the longitudinal axis would include channels 102a (figure 6) in the orthogonal direction to the longitudinal axis 23 and where these channels form shapes that are ovoid and conical or pyramidal (figures 8-10) (re claims 4-8,10,30-34 and 36). The occluder is taught as being movable through a catheter where its end is mechanically engaged by a pusher head, which is a severable joint, at which is electrically detachable (from column 9, line 51) (re claims 14,15,40 and 41). The occluding element is further provided with a radio-opaque material for making it visible fluoroscopically (column 7, lines 40-45) where it can include an appropriate radio-opaque resin material (re claims 24 and 45) or a metal such as tantalum (re claim 46). However, Marotta et al. do not suggest the initial tube material as being formed by injection molding of a plastic tube with specific absorptive qualities.

Igaki teaches a vascular device where the device 12 is comprised by a tube, which is micro-machined to include a plurality of bores therein. Further, Igaki teaches the tube being formed of a polymer which has biological compatibility and including absorptive qualities of polylactic acid (re claims 2,3,28 and 29) and being formed by injection molding (from column 4, lines 55-59) (re claims 1 and 48).

It would have been obvious to a person having ordinary skill in the art of surgical occluders at the time of applicant's invention to construct the initial micro-machined tube of Marotta et al. as including a tube formed by injection molded and including absorptive qualities. Providing such a tube construction would assure the proper size and specific shape needed in the initial tube. Providing the specific absorptive quality would allow a quicker recovery for the patient since thrombosis of the aneurysm would be speeded up.

Claims 18 and 44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Marotta et al., as modified above by Igaki and further in view of Ken (6,293,960).

Marotta et al., as modified above by Igaki, disclose the invention substantially as claimed. Marotta et al., as modified above by Igaki, teach a vaso-occlusive prosthesis and method for forming the device. Marotta et al. teach an occlusive element 105 (figure 6, for example) comprising a three-dimensional configuration. T he occluder is taught as being movable through a catheter where its end is mechanically engaged by a pusher head, which is a severable joint, at which is electrically detachable (from column 9, line 51). However, Marotta et al., as modified above by Igaki do not suggest the occluder as including an electromagnetic means for disconnection to the pusher.

Ken teaches a vaso-occlusive device where the device 32 is comprised by a balloon, which is attached to a pusher rod for placement at an aneurysm. Further, Ken teaches the connection between the pusher 26 and the balloon as including a connection such that is disconnectable by electromagnetic means (from column 3, lines 3-5).

It would have been obvious to a person having ordinary skill in the art of surgical occluders at the time of applicant's invention to construct the connection between the occluder of Marotta et al., as modified by Igaki, as including an electromagnetic disconnection means. Providing such a disconnection would reduce the trauma on the patient sine the body is more able to take this procedure and the connection would be easily broken as desired.

PERTINENT CITATIONS

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Talja et al., and Straight illustrate injection-molded elements in a variety of shapes. Ken et al., and Akerfeldt illustrate three dimensional vaso occlusive elements with Akerfeldt further illustrating an injection-molded element. Brumlik illustrates the chemical etching of injection-molded elements.

INQUIRIES

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Ismael Izaguirre located in CP2-4B18 and whose telephone number is (703) 308-0892. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

Ismael Izaguirre

Primary Examiner

Art Unit 3765

II

December 27, 2003